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7 MEHVA ROFFMAN, et al.,
8 Plaintiffs,
9 v.
10 PERFECT BAR, LLC,
11 Defendant.

Case No. 22-cv-02479-JSC

12
13 **ORDER RE: MOTION TO DISMISS**

14 Re: Dkt. No. 18

15 Plaintiffs are consumers who challenge Defendant's claims on its product labels about the
16 amount of protein they contain. (Dkt. No. 1.)¹ Before the Court is Defendant's motion to dismiss.
17 (Dkt. No. 18.) Having carefully considered the parties' briefing, and with the benefit of oral
18 argument on August 31, 2022, the Court GRANTS the motion.

19 **COMPLAINT ALLEGATIONS**

20 Defendant makes claims on the front labels of its food products about the amount of
21 protein they contain. The front label of the Perfect Bar in Dark Chocolate Chip Peanut Butter
22 flavor says "15G PROTEIN," and the front label of the Perfect Peanut Butter Cups Dark
23 Chocolate flavor says "7G PROTEIN." (Dkt. No. 1 ¶¶ 2, 18.) Plaintiff Ms. Chong bought the
24 Perfect Bar in Dark Chocolate Chip Peanut Butter flavor at stores around the Bay Area between
25 2018 and 2022. (*Id.* ¶ 15.) Plaintiff Ms. Roffman bought Perfect Peanut Butter Cups in Dark
26 Chocolate and Milk Chocolate flavors at stores around the Bay Area between 2019 and 2022. (*Id.*
27 ¶ 59.)

28 Each Plaintiff "read[]" and "relied on" the "front labels that promised" "7G PROTEIN,"

¹ Record citations are to material in the Electronic Case File ("ECF"); pinpoint citations are to the ECF-generated page numbers at the top of the documents.

1 “8G PROTEIN,” and “15G PROTEIN,” “believ[ing] . . . that the product would actually provide
2 her the specific amount of protein on the front label in a form her body could utilize as protein.”
3 (*Id.* ¶¶ 56, 60; *see id.* ¶ 2.) But “not all proteins are the same in their ability to meet human
4 nutritional requirements, so a simple statement about the number of grams does not actually
5 inform consumers about how much usable protein they are receiving.” (*Id.* ¶ 3.)

6 Some proteins are deficient in one or more of the nine amino acids
7 essential to human protein synthesis and/or are not fully digestible
8 within the human gut. When a human body uses up the least prevalent
9 essential amino acid from a food product, protein synthesis shuts
10 down and all of the remaining amino acids from that protein source
degrade mostly into waste. Likewise, whatever portion of a protein
source is not digestible is similarly unavailable for protein synthesis.
A protein’s ability to support human nutritional requirements is
known as its “quality.”

11 (*Id.*; *see id.* ¶¶ 25–28.) The “Protein Digestibility Corrected Amino Acid Score” (“PDCAAS”),
12 also known as the “corrected amount of protein per serving,” is a method for measuring protein
13 quality. (*Id.* ¶ 4.) PDCAAS “combines a protein source’s amino acid profile and its percent
14 digestibility into a discount factor ranging from 0.0 to 1.0 that, when multiplied by the total
15 protein quantity, shows how much protein in a product is actually available to support human
16 nutritional requirements.” (*Id.*) For example, nuts, the primary protein source in Defendant’s
17 products, have a PDCAAS score of 0.4–0.5, meaning that only 40–50% of the protein is “actually
18 available to support human protein needs.” (*Id.* ¶ 5.) PDCAAS can also be expressed as a percent
19 daily value, meaning “the corrected amount of protein per serving divided by the daily reference
20 value for protein of 50 grams.” (*Id.* ¶ 4.) For example, a product with 10 grams of protein and a
21 PDCAAS score of 0.5 would have a percent daily value of 10%: 10 grams multiplied by 0.5,
22 divided by 50 grams. (*See id.*)

23 Plaintiffs allege Defendant’s front-label claims, like “15G PROTEIN,” are misleading
24 because they provide only a quantitative amount without any information about protein quality.
25 They also challenge Defendant’s failure to include, in the nutrition facts panel on the back of its
26 products, information about protein quality in the form of a percent daily value. (*See id.* ¶ 19.)
27 Defendant’s protein claims caused Plaintiffs “to pay a price premium for the products.” (*Id.* ¶ 7.)
28 Had Defendant not misrepresented the products, Plaintiffs “would not have purchased them or, at

1 a very minimum, [they] would have paid less.” (*Id.* ¶¶ 57–58, 61–63.)

2 Plaintiffs filed suit on behalf of a nationwide class and California subclass. (*Id.* ¶ 64.)
3 They bring claims under California law for violations of the Consumers Legal Remedies Act
4 (“CLRA”), False Advertising Law (“FAL”), and Unfair Competition Law (“UCL”); fraud; and
5 unjust enrichment. Plaintiffs disclaim any causes of action under the Federal Food, Drug, and
6 Cosmetic Act (“FDCA”) and its regulations, relying on them only to the extent they are also
7 enacted under state law or provide a predicate for liability under state law. (*See id.* at 21.)

8 DISCUSSION

9 Plaintiffs have three theories of liability. Defendant argues that each theory is expressly or
10 impliedly preempted by the FDCA, and that Plaintiffs do not sufficiently allege reliance on the
11 product labels.

12 **I. Are the Front-Label Protein Claims Unlawful Without Corresponding Figures on the 13 Nutrition Facts Panel?**

14 Plaintiffs’ first theory is that Defendant’s front-label protein claims do not comply with 21
15 C.F.R. §§ 101.9(c)(7)(i) and 101.13(n), Food and Drug Administration (“FDA”) regulations
16 implementing the FDCA. These allegations serve as a predicate for violating California laws,
17 including the Sherman Law, which in turn serve as a predicate for violating the “unlawful” prong
18 of the UCL. (Dkt. No. 20 at 12–13; Dkt. No. 1 ¶¶ 100–01); *see Morgan v. Wallaby Yogurt Co.,*
19 *Inc.*, No. 13-cv-00296-WHO, 2013 WL 5514563, at *5 (N.D. Cal. Oct. 4, 2013) (noting that
20 California’s Sherman Law incorporates the FDCA and can form the basis for a UCL unlawful
21 prong claim).

22 **A. Express Preemption**

23 The FDCA, as amended, expressly preempts state claims that are “not identical to” its own
24 requirements. 21 U.S.C. § 343-1(a); *see Hawkins v. Kroger Co.*, 906 F.3d 763, 769–70 (9th Cir.
25 2018); *Reid v. Johnson & Johnson*, 780 F.3d 952, 959–60 (9th Cir. 2015). Thus, if the FDCA or
26 FDA regulations do not prohibit Defendant’s conduct as alleged in the complaint, then Plaintiffs’
27 state law claims are expressly preempted. *See Hawkins*, 906 F.3d at 769–70; *see also Durnford v.*
28 *MusclePharm Corp.*, 907 F.3d 595, 602 (9th Cir. 2018) (noting that “FDA regulations . . . have the

1 same preemptive effect as a statute"); *Gitson v. Trader Joe's Co.*, No. 13-1333, 2015 WL
2 9121232, at *1 (N.D. Cal. Dec. 1, 2015) ("[W]hen it comes to food labels, state law may only
3 impose liability for what the federal statute proscribes.").

4 Section 101.9 regulates the information that appears in the nutrition facts panel on the back
5 or side of a food product's packaging. With respect to protein:

6 (c) The declaration of nutrition information on the label and in
7 labeling of a food shall contain information about the level of the
following nutrients . . .

8 (7) "Protein": A statement of the number of grams of protein in a
9 serving, expressed to the nearest gram . . . Protein content may be
calculated on the basis of the factor 6.25 times the nitrogen content of
10 the food . . .

11 (i) A statement of the corrected amount of protein per serving, as
12 determined in paragraph (c)(7)(ii) of this section, . . . expressed as
Percent of Daily Value, may be placed on the label, except that such
a statement shall be given if a protein claim is made for the product .
13 . . . When such a declaration is provided, it should be placed on the
label adjacent to the statement of grams of protein and aligned under
14 the column headed "Percent Daily Value," and expressed to the
nearest whole percent.

15 21 C.F.R. § 101.9(c)(7)(i). Thus, "the number of grams of protein in a serving" "shall" appear on
16 the nutrition facts panel. *Id.* §§ 101.9(c)(7), 101.9(c). That figure "may" be calculated using what
17 the parties call the nitrogen method. *Id.* § 101.9(c)(7); *see Durnford*, 907 F.3d at 603. An
18 alternative figure "may" be calculated using the PDCAAS, referred to in the regulations as "the
19 corrected amount of protein per serving," expressed as a percent daily value. 21 C.F.R. §
20 101.9(c)(7)(i). But if "a protein claim is made," then a figure calculated using the PDCAAS,
21 expressed as a percent daily value, "shall" appear on the nutrition facts panel. *Id.* § 101.9(c)(7).

22 Section 101.13 regulates the information that appears elsewhere on the food product's
23 packaging. As relevant to Section 101.9, Section 101.13 explains what a "protein claim" is:

24 Information that is required or permitted by § 101.9 or § 101.36, as
25 applicable, to be declared in nutrition labeling, and that appears as
part of the nutrition label, is not a nutrient content claim and is not
26 subject to the requirements of this section. If such information is
declared elsewhere on the label or in labeling, it is a nutrient content
27 claim and is subject to the requirements for nutrient content claims.

28 21 C.F.R. § 101.13(c); *see Reid*, 780 F.3d at 959 ("[T]he general rule is that 'nutrient content

1 claims’ are not permitted on food labels. . . . However, the regulations do authorize some nutrient
2 content claims. . . . While a required statement inside a nutrition [facts panel] escapes regulations
3 reserved for nutrient content claims, the identical statement outside of the nutrition [facts panel] is
4 still considered a nutrient content claim and is therefore subject to section 101.13.”). Thus,
5 information about protein that is required or permitted by Section 101.9, but that appears
6 somewhere other than the nutrition facts panel, is a “protein claim” “subject to the requirements
7 for nutrient content claims.” 21 C.F.R. §§ 101.9(c)(7)(i), 101.13(c); *see id.* § 101.13(n)
8 (“Nutrition labeling in accordance with § 101.9 . . . shall be provided for any food for which a
9 nutrient content claim is made.”).

10 Plaintiffs allege that Defendant states the amount of protein, calculated using the nitrogen
11 method, on the front label of its products. (Dkt. No. 1 ¶ 18.) The amount of protein, calculated
12 using the nitrogen method, is “permitted by § 101.9 . . . to be declared in nutrition labeling,”
13 meaning the nutrition facts panel. 21 C.F.R. § 101.13(c). Because Plaintiffs allege it appears
14 “elsewhere”—on the front label—“it is a nutrient content claim and is subject to the requirements
15 for nutrient content claims.” *Id.* One such requirement is that “if a protein claim is made,” then
16 the amount of protein, calculated using the PDCAAS and expressed as a percent daily value,
17 “shall” appear on the nutrition facts panel. *Id.* § 101.9(c)(7). Plaintiffs allege no such information
18 appears on the nutrition facts panel of Defendant’s products. (Dkt. No. 1 ¶ 19.) Thus, Plaintiffs
19 plausibly allege Defendant’s conduct does not comply with Section 101.9(c)(7) because it puts
20 nitrogen-method protein claims on the front label without the corresponding PDCAAS figures on
21 the nutrition facts panel. (*See id.* ¶¶ 74 (“Defendant had a duty to disclose the corrected amount of
22 protein per serving for all the Products in the [nutrition facts panel] as calculated by the PDCAAS
23 method, which Defendant failed to do.”), 80, 90, 101.)

24 Courts in this District have not yet considered this particular theory. The closest case is
25 *Brown v. Van’s International Foods, Inc.* (“Van’s”), No. 22-cv-00001-WHO, 2022 WL 1471454
26 (N.D. Cal. May 10, 2022), in which the court initially granted the defendant’s motion to dismiss:

27 [Plaintiff] contends that a protein claim unadjusted for digestibility is
28 inherently misleading, but this legal theory is preempted by the
[FDCA]. Her claims based on this first theory are dismissed with

prejudice. . . . During the hearing, [Plaintiff] advanced a third theory that the front-label protein claim is unlawful because it violates 21 C.F.R. § 101.13(n). While at a first glance this argument appears plausible, I will not discuss it in this Order.

Id. at *1. The plaintiff then filed an amended complaint, which advanced the latter theory of unlawfulness. *See Van's*, 2022 WL 3590333 (N.D. Cal. Aug. 22, 2022). The defendant moved to dismiss for failure to plead reliance; the court denied the motion on those grounds, and had no occasion to analyze whether the plaintiff's unlawfulness theory stated a viable claim for relief. *See id.*

Defendant argues it is illogical to interpret the FDA regulations to allow one protein figure on the front label and require a different figure on the nutrition facts panel. But that is precisely what the regulations do. *See* 21 C.F.R. § 101.13(c) (allowing a nitrogen-method figure for a front-label protein claim); *id.* § 101.9(c)(7) (requiring a PDCAAS figure on the nutrition facts panel). Courts considering other theories have noted in passing that the regulations require that if a product has a front-label protein claim, it must have a corresponding PDCAAS figure on the nutrition facts panel. *See Chong v. Kind LLC*, No. 21-cv-04528-RS, 2022 WL 464149, at *3 (N.D. Cal. Feb. 15, 2022) (“If a producer makes a protein nutrient claim, however, it must also provide a ‘% Daily Value’ in the Nutrition Facts panel. That ‘% Daily Value’ must be calculated using the PDCAAS”); *Nacarino v. Kashi Co.* (“*Nacarino*”), No. 21-cv-07036-VC, 2022 WL 390815, at *4 (N.D. Cal. Feb. 9, 2022) (“[T]he FDA recognizes that in situations where consumers are drawn to a product for its protein content—those situations in which a manufacturer is touting its product’s protein on its packaging—consumers deserve additional information in the Nutrition Facts label.”), *appeal filed*, No. 22-15377 (9th Cir. Mar. 14, 2022).

Accordingly, Plaintiffs plausibly allege that the front-label protein claims are unlawful without corresponding PDCAAS figures on the nutrition facts panel. Because the alleged conduct is prohibited by FDA regulations, state law claims based on that conduct are not expressly preempted. *See Hawkins*, 906 F.3d at 769–70.

B. Implied Preemption

As for implied preemption, Defendant relies on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). *Buckman* held that there may be conflict preemption, a

1 “subcategor[y] of implied preemption,” where there is an actual conflict between state law claims
2 and the FDCA, as amended. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en
3 banc); *see McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039–40 (9th Cir. 2015). Thus, the
4 *Buckman* plaintiffs’ state law claims that the defendant “made fraudulent representations to the
5 FDA, resulting in improper market clearance for bone screws,” conflicted with the FDCA’s
6 scheme for deterring fraud in the market clearance process. *McClellan*, 776 F.3d at 1039; *see*
7 *Buckman*, 531 U.S. at 348 (“The conflict stems from the fact that the federal statutory scheme
8 amply empowers the FDA to punish and deter fraud against the Administration, and that this
9 authority is used by the Administration to achieve a somewhat delicate balance of statutory
10 objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-
11 FDA claims under state tort law.”). *Buckman* “left the door open to state-law claims parallel to
12 federal requirements.” *McClellan*, 776 F.3d at 1040 (cleaned up).

13 Plaintiffs’ theory parallels federal requirements. Plaintiffs assert that Defendant’s front-
14 label protein claims, without corresponding figures on the nutrition facts panel, violate California
15 laws including the Sherman Law, and thus violate the “unlawful” prong of California’s UCL.
16 Therefore, their theory parallels the requirements of Sections 101.9(c)(7)(i) and 101.13(n). *See*
17 *Stengel*, 704 F.3d at 1228 (“[The FDCA, as amended,] does not preempt a state-law claim for
18 violating a state-law duty that parallels a federal-law duty under the [FDCA].”); *Morgan*, 2013
19 WL 5514563, at *5 (“[T]he state law mirrors the federal law, so a private party would not find it
20 impossible to comply with both”). And because it parallels federal requirements, it presents
21 no obstacle to Congress’s objectives in enacting the FDCA. *See Morgan*, 2013 WL 5514563, at
22 *5 (“Congress has expressly allowed state laws regulating food labeling so long as they are not
23 expressly preempted; thus, the Sherman Law is not an obstacle to Congress’s purpose and
24 objectives.”).

25 *Buckman* also held that claims that directly seek to enforce the FDCA are impliedly
26 preempted. The FDCA contains no private right of action, so a plaintiff cannot sue directly to
27 enforce its requirements. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013). But there
28 is a “narrow gap” that avoids preemption: claims challenging “conduct that violates the FDCA,”

1 “but not *because* the conduct violates the FDCA.” *Id.* at 1120 (cleaned up). Plaintiffs’ theory fits
2 through that narrow gap. They disclaim any cause of action under the FDCA, (*see* Dkt. No. 1 at
3 21), but challenge conduct that violates it. *Cf. Van’s*, 2022 WL 1471454, at *7 (“In other words,
4 [Plaintiff] is suing because the protein statements at issue are allegedly misleading under
5 California law, not because the protein statements allegedly violate FDA regulations.”).

6 Finally, there is a strong general presumption against preemption: “[W]e start with the
7 assumption that the historic police powers of the States were not to be superseded by the Federal
8 Act unless that was the clear and manifest purpose of Congress.” *Wyeth v. Levine*, 555 U.S. 555,
9 565 (2009) (cleaned up). That presumption applies here, because the states’ historic police powers
10 have included “the power to protect their citizens from fraud and deception in the sale of food.”
11 *Clancy v. The Bromley Tea Co.*, 308 F.R.D. 564, 573 (N.D. Cal. 2013); *see Stengel*, 704 F.3d at
12 1228 (noting that states’ power “to protect the health and safety of their citizens” is “primarily,
13 and historically, [a] matter[] of local concern” (cleaned up)). Defendant has not overcome that
14 presumption.

15 Accordingly, Plaintiffs’ state law claims based on the theory that Defendant’s front-label
16 protein claims are unlawful without corresponding PDCAAS figures on the nutrition facts panel
17 are not impliedly preempted under *Buckman*. *See Van’s*, 2022 WL 1471454, at *6–8 (finding no
18 implied preemption of plaintiffs’ protein labeling claims, and collecting cases).

19 C. Reliance

20 Finally, Defendant argues that this theory is not supported by plausible allegations of
21 reliance.

22 As a matter of statutory standing for misrepresentation or fraud claims under the CLRA,
23 UCL, and FAL, a plaintiff must have “actually relied on whatever defect in a product label
24 allegedly makes it actionable when making her decision to buy the product.” *Shaeffer v. Califia*
25 *Farms, LLC*, 258 Cal. Rptr. 3d 270, 283 (Cal. Ct. App. 2020) (cleaned up); *see Moore v. Mars*
26 *Petcare US, Inc.*, 966 F.3d 1007, 1020 (9th Cir. 2020) (“Since the passage of Proposition 64, a
27 plaintiff must allege actual reliance in order to have standing to pursue UCL and FAL claims.”).
28 “To satisfy this requirement, she must truthfully allege that she would not have bought the product

1 but for the allegedly actionable misrepresentation or omission.” *Shaeffer*, 258 Cal. Rptr. 3d at 283
2 (cleaned up). The requirement also applies for a claim under the UCL’s unlawful prong if the
3 underlying conduct is a misrepresentation or fraud. *See Kwikset Corp. v. Superior Court*, 246
4 P.3d 877, 888 n.9 (Cal. 2011); *Van’s*, 2022 WL 3590333, at *4 (collecting cases); *see generally*
5 *Cel-Tech Comms., Inc. v. L.A. Cellular Telephone Co.*, 973 P.2d 527, 539–40 (Cal. 1999) (“By
6 proscribing ‘any unlawful’ business practice, [the UCL] borrows violations of other laws and
7 treats them as unlawful practices that the [UCL] makes independently actionable.” (cleaned up)).

8 Here, Plaintiffs’ first theory is that the front-label protein claims are unlawful without
9 corresponding PDCAAS figures—whether or not they are misleading. *See Cel-Tech*, 973 P.2d at
10 540 (“Because [the UCL] is written in the disjunctive, it establishes three varieties of unfair
11 competition—acts or practices which are unlawful, or unfair, or fraudulent. In other words, a
12 practice is prohibited as unfair or deceptive even if not unlawful and vice versa.” (cleaned up)).
13 The Court concludes that the reliance requirement also applies to a claim under the UCL’s
14 unlawful prong where the underlying conduct is not a misrepresentation or fraud. *See Van’s*, 2022
15 WL 3590333, at *4–5 (analyzing issue but declining to rule on it because the plaintiff sufficiently
16 alleged reliance regardless); *Nacarino v. Chobani, LLC*, No. 20-cv-07437-EMC, 2022 WL
17 344966, at *6 (N.D. Cal. Feb. 4, 2022) (“[The reliance requirement] appears true of all UCL
18 claims, regardless of whether they are brought under the unfair, unlawful, or fraudulent prong.”).
19 While *Kwikset* declined to reach this issue, *see* 246 P.3d at 888 n.9, there is no reason to limit its
20 principle—that reliance is a matter of causation—to misrepresentation or fraud. *See Kane v.*
21 *Chobani, Inc.*, No. 12–CV–02425–LHK, 2013 WL 5289253, at *8–10 (N.D. Cal. Sept. 19, 2013)
22 (“Were the Court to hold that Plaintiffs, who never viewed the No Sugar Added Representations,
23 have standing to bring claims based solely upon allegations that they would not have purchased a
24 product that was misbranded, purchasers who never viewed the defendant’s advertising or
25 misleading labeling would have standing to sue. Such a holding is inconsistent with Proposition
26 64 and *Kwikset*.” (cleaned up)); *see also Moore*, 966 F.3d at 1020 (stating that reliance is a
27 requirement for UCL claims, but applying the requirement specifically to a misrepresentation
28 claim).

1 Thus, Plaintiffs must allege actual reliance. And because their theory is that the front-label
2 protein claim is unlawful *without* a corresponding figure on the nutrition facts panel, they must
3 allege they relied on the nutrition facts panel's omission. Under Plaintiffs' theory, the front-label
4 protein claim may have been lawful if there was a corresponding figure on the nutrition facts
5 panel. Therefore, without an allegation that Plaintiffs ever looked at the nutrition facts panel—and
6 thus ever knew one way or the other if the nutrition facts panel had a corresponding figure—there
7 is no causal link between the allegedly unlawful front-label protein claim and Plaintiffs' alleged
8 harm. *See Shaeffer*, 258 Cal. Rptr. 3d at 278 (explaining that reliance is a matter of causation).

9 The complaint alleges each Plaintiff “read[]” and “relied on” the “front labels that
10 promised” “7G PROTEIN,” “8G PROTEIN,” and “15G PROTEIN,” “believ[ing] . . . that the
11 product would actually provide her the specific amount of protein on the front label in a form her
12 body could utilize as protein.” (Dkt. No. 1 ¶¶ 56, 60; *see id.* ¶ 2.) It does not allege that Plaintiffs
13 looked at or relied on the nutrition facts panel, only that the nutrition facts panel failed to include a
14 PDCAAS figure. (*See id.* ¶ 19.) As such, the complaint does not plausibly allege reliance on the
15 nutrition facts panel. *See Brown v. Natures Path Foods, Inc.*, No. 21-cv-05132-HSG, 2022 WL
16 717816, at *4 (N.D. Cal. Mar. 10, 2022) (“the Complaint does not allege that Plaintiffs ever
17 reviewed the nutrition facts labels before buying the Products and therefore fails to allege that they
18 relied on the absence of the ‘percent daily value’ figure to their detriment”). Accordingly, the
19 complaint does not establish Plaintiffs’ standing to pursue claims based on this theory.

20 Plaintiffs acknowledge they have not alleged reliance on the nutrition facts panel, but say
21 they could amend their complaint to do so. Defendant's argument that the defects could not be
22 cured by amendment does not make sense; that Plaintiffs relied on the front-label protein claims
23 does not mean that they could not also have read and relied on the nutrition facts panel and its
24 omission.

25 * * *

26 Plaintiffs' claims based on the theory that Defendant's front-label protein claims do not

27 comply with Sections 101.9(c)(7) and 101.13(n) are not expressly or impliedly preempted.

28 However, Plaintiffs have not established their standing to pursue those claims because they have

1 not adequately alleged reliance on the nutrition facts panel and its omission. Accordingly,
2 Defendant's motion to dismiss is GRANTED as to claims based on this theory, with leave to
3 amend so that Plaintiffs may allege what they read and relied on, if anything, in the nutrition facts
4 panel. *See Van's*, 2022 WL 1471454, at *9–10 (dismissing for failure to allege reliance and
5 granting leave to amend).

6 **II. Are the Front-Label Protein Claims Misleading?**

7 Plaintiffs separately allege that Defendant's front-label protein claims are misleading,
8 deceptive, and fraudulent. The FDCA prohibits food labeling that is "false or misleading," and
9 FDA regulations specifically prohibit nutrient claims that are "false or misleading in any respect."
10 21 U.S.C. 343(a); 21 C.F.R. § 101.13(i)(3). Plaintiffs' allegations serve as a predicate for
11 violating the CLRA, the FAL, and the fraud prong of the UCL, as well as for common law fraud
12 and unjust enrichment. (Dkt. No. 1 ¶¶ 74, 80, 90, 101, 115.) In turn, some of those violations also
13 serve as predicates for the unlawful prong of the UCL. (*Id.* ¶ 100.) Plaintiffs characterize these as
14 "two distinct deception/fraud theories":

15 First, the Complaint alleges that Perfect Bar's front label claims,
16 which omit a statement of the corrected amount of protein in the
17 [nutrition facts panel], are deceptive because they lead consumers to
18 believe that all the advertised protein will be bioavailable. Second,
the Complaint alleges that Perfect Bar's standalone, nitrogen-based
protein quantity claims on the front label are misleading by virtue of
the low quality protein in Perfect Bar's products.

19 (Dkt. No. 20 at 19.)

20 **A. Misleading Because of Omitted PDCAAS Figure on the Nutrition Facts Panel**

21 Plaintiffs' first deception theory is that Defendant's nitrogen-method front-label protein
22 claims are misleading because, without the required PDCAAS figures on the nutrition facts panel,
23 consumers will believe that the full amount of protein is "bioavailable" or digestible.

24 **1. Express Preemption**

25 Defendant has met its burden of showing that Plaintiffs' claim that the omission of
26 PDCAAS figures is misleading is expressly preempted. It is preempted because the FDA
27 regulations expressly allow a manufacturer to put a nitrogen-method figure on the nutrition facts
28 panel without any other information about protein anywhere on the product. *See* 21 C.F.R. §

1 101.9(c)(7); *see also Durnford*, 907 F.3d at 603 (“[F]ederal regulations allow nitrogen to be used
2 on the nutrition panel as a proxy for protein content.”). Since the regulations allow a nitrogen-
3 method figure on the nutrition facts panel without any other information, Plaintiffs’ claim that the
4 nitrogen-method figure on the front label without any other information is misleading conflicts
5 with and is not identical to FDA regulations and is thus preempted. To put it another way, since
6 FDA regulations prohibit misleading labeling, *see 21 C.F.R. § 101.13(i)(3)*, and FDA regulations
7 permit a nitrogen-method figure, *see id. § 101.9(c)(7)*, the nitrogen-method figure is not
8 misleading under the FDA regulations. Thus, to find that the nitrogen-method figure is misleading
9 would conflict with FDA regulations. *See Nacarino*, 2022 WL 390815, at *4. *But see Van’s*,
10 2022 WL 1471454, at *6 (concluding this theory is plausible and not expressly preempted).

11 Accordingly, because this theory challenges conduct permitted by the FDCA and FDA
12 regulations, it is expressly preempted. *See Hawkins*, 906 F.3d at 769–70.

13 * * *

14 Plaintiffs’ claims based on the theory that Defendant’s front-label protein claims are
15 misleading without the corresponding PDCAAS figures on the nutrition facts panel are expressly
16 preempted. Accordingly, Defendant’s motion to dismiss is GRANTED as to claims based on this
17 theory. The dismissal is without leave to amend because the defect is in the legal theory, not the
18 factual allegations.

19 **B. Misleading In and Of Themselves**

20 Plaintiffs’ second deception theory is that Defendant’s nitrogen-method front-label protein
21 claims are misleading in and of themselves. Plaintiffs say their position is limited to low-quality
22 protein products like Defendant’s, because nitrogen-method protein claims for high-quality protein
23 products are less apt to mislead about the product’s protein digestibility. (Dkt. No. 20 at 28.)

24 **1. Express Preemption**

25 For the reasons thoroughly explained by other courts in this District, the FDCA expressly
26 preempts any claim that Defendant’s nitrogen-method front-label protein claims are misleading in
27 and of themselves.

28 Because the FDCA regulations allow protein claims to be calculated with the nitrogen

1 method, such claims cannot be misleading in and of themselves as a matter of law. *See* 21 C.F.R.
2 § 101.13(o) (“compliance with requirements for nutrient content claims . . . will be determined
3 using the analytical methodology prescribed for determining compliance with nutrition labeling in
4 § 101.9”); *id.* § 101.9(c)(7) (providing that the nitrogen method and PDCAAS may be used to
5 determine compliance with nutrition labeling). “[T]o find that an FDA-approved protein
6 measurement technique is inherently misleading . . . is not a plausible interpretation of the
7 regulations.” *Nacarino*, 2022 WL 390815, at *4. Thus, the FDCA preempts Plaintiffs’ attempt to
8 use state law to impose requirements that the FDCA does not. *See Van’s*, 2022 WL 1471454, at
9 *5–6 (finding preempted theory that “the claim misleadingly advertises a specific amount of
10 protein per serving without adjusting for digestibility”); *Chong*, 2022 WL 464149, at *2–3 (same);
11 *Nacarino*, 2022 WL 390815, at *3–5 (finding preempted theory that “the nitrogen-content method
12 [] overstates the amount of protein per serving” and that it is “misleading to use a figure . . . that
13 has not been adjusted for protein digestibility”).

14 A few cases from other district courts that have held the FDCA does not preempt this
15 theory. *See Ulrich v. Probalance, Inc.*, No. 16 C 10488, 2017 WL 3581183, *5 (N.D. Ill. Aug. 18,
16 2017) (“[E]ven if the regulations do not *require* manufacturers to calculate protein content by the
17 PDCAAS-adjusted method, it may nevertheless be misleading in a particular context to use the
18 nitrogen method, and misleading labeling violates the FDCA and accompanying regulations.”);
19 *Porter v. NBTY, Inc.*, No. 15 CV 11459, 2016 WL 6948379, *6 (N.D. Ill. Nov. 28, 2016)
20 (“Because defendants were required to calculate the corrected amount of protein (so they could
21 comply with the protein-claim regulation), they knew that the statement ‘60g Premium Protein’
22 was not accurate. This is sufficient to state a claim that the front-label statement is false or
23 misleading”). These cases are not persuasive because the FDA regulations allow the nitrogen
24 method for front-label protein claims, with no distinction based on low- or high-quality protein.
25 That the regulations simultaneously prohibit “misleading” labeling, 21 C.F.R. § 101.13(i)(3),
26 shows that nitrogen-method protein claims are not inherently misleading under the FDA
27 regulations.

28 Finally, the FDA recently issued guidance stating that, under Section 101.9(c)(7), “either”

1 the nitrogen method or the PDCAAS method may be used “when calculating protein values for
2 use in protein nutrient content claims.” (Dkt. No. 19-1 at 13.)² Thus, the guidance indicates that
3 the FDA does not consider nitrogen-method front-label protein claims to be misleading in and of
4 themselves. The guidance is persuasive authority on this point, but it is not necessary to the
5 Court’s conclusion. *See Van’s*, 2022 WL 1471454, at *5 & n.2; *Nacarino*, 2022 WL 390815, at
6 *4 & n.4.

7 * * *

8 Plaintiffs’ theory that the nitrogen-method front label protein claims are misleading in and
9 of themselves is expressly preempted by the FDCA. Accordingly, Defendant’s motion to dismiss
10 is GRANTED as to Plaintiffs’ claims based on the theory that the nitrogen-method front-label
11 protein claims are misleading in and of themselves and/or because of the low-quality protein
12 contained in the products. The dismissal is without leave to amend because the defect is in the
13 legal theory, not the factual allegations.

14 CONCLUSION

15 Defendant’s motion is GRANTED.

16 Plaintiffs’ claims based on (1) the theory that Defendant’s front-label protein claims do not
17 comply with Sections 101.9(c)(7) and 101.13(n) are dismissed WITH leave to amend. Plaintiffs’
18 claims based on (2) the theory that Defendant’s front-label protein claims are misleading without
19 the corresponding PDCAAS figures on the nutrition facts panel and (3) the theory that

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21 ² Defendant’s request for judicial notice is GRANTED in part and DENIED in part. (Dkt. No.
19.)

22 The Court takes judicial notice of the 2022 FDA guidance, (Dkt. No. 19-1). *See King v.*
23 *County of Los Angeles*, 885 F.3d 548, 555 (9th Cir. 2018) (noting that courts may take judicial
24 notice of “undisputed and publicly available information displayed on government websites”); *see also Van’s*, 2022 WL 1471454, at *5 n.2 (taking judicial notice of 2022 FDA guidance);
Nacarino, 2022 WL 390815, at *4 n.3 (same).

25 However, the Court declines to take judicial notice of emails between FDA representatives
26 and attorneys for manufacturers who make protein claims on their products. (Dkt. Nos. 19-2, 19-
27 3.) The emails are private responses to private inquiries; they are not matters of public record and
28 do not give the FDA’s official interpretation of the FDCA or its regulations. *See Lee v. City of Los*
Angeles, 250 F.3d 668, 689–90 (9th Cir. 2001); *cf. Von Koenig v. Snapple Beverage Corp.*, 713 F.
Supp. 2d 1066, 1073 (E.D. Cal. 2010) (taking judicial notice of FDA letters that were issued as
public records).

1 Defendant's front-label protein claims are misleading in and of themselves and/or because of the
2 low-quality protein contained in the products are dismissed WITHOUT leave to amend. Plaintiffs
3 may file an amended complaint on or before October 3, 2022.

4 The Court will hold an initial case management conference on November 3, 2022 at 1:30
5 p.m. via Zoom video. An updated joint case management conference statement with a proposed
6 schedule with actual dates through class certification is due one week in advance.

7 This Order disposes of Docket No. 18.

8 **IT IS SO ORDERED.**

9 Dated: September 2, 2022

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13 JACQUELINE SCOTT CORLEY
14 United States District Judge
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